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TITLE: DEVELOPMENT OF MEDICAL ADJUNCTIVE TREATMENT ACUTE
PENETRATING HEAD INJURY

PRINCIPAL INVESTIGATOR: Andres M. Salazar, M.D.

CONTRACTING ORGANIZATION: Uniformed Services University
of Health Sciences
4301 Jones Bridge Road
Bethesda, MD 20814-4799

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FOREWORD

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4301 JONES BRIDGE ROAD
BETHESDA, MARYLAND 20814-4799



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ANNUAL REPORT (1 November 1988 — 21 November 1989)
ARMY PENETRATING HEAD INJURY PROJECT (APHIP), 87PP7824
Uniformed Services University of the Health Sciences
Andres M. Salazar, M.D., COL, MC, USA
Director, Army Head Injury Unit
ATTN: HSHL-CI, Walter Reed Army Medical Center
Washington, DC 20307-5001
202-576-1348/1345

ABSTRACT

Head injury is the principal cause of death and disability in young adults today. While it is a major cause of combat mortality and accounts for a significant proportion of combat casualty care resources, young survivors nevertheless may have a relatively good prognosis. Acute intracranial debridement of missile tracts has been the traditionally accepted management for patients with penetrating brain injuries, but more recent experience has questioned the need and value of this approach in most cases. At the same time, delayed secondary injury mediated by a variety of biochemical changes has come to be recognized as a major contributor to mortality and morbidity after head trauma. The principal objective of this clinical project is to develop medical adjunctive treatments for this secondary injury that will not only minimize or delay the need for extensive surgery in the area of missile penetration and minimize ultimate tissue loss, but can also be used to manage inaccessible lesions and more diffuse secondary injury not amenable to surgery.

The Army Penetrating Head Injury Project (APHIP) is a coordinated, multicenter clinical consortium now established to conduct serial therapeutic trials in head injured patients. An initial descriptive study of penetrating head injury is ongoing, and a therapeutic trial of a promising new agent, superoxide dismutase, is now in very advanced planning.

Hypotheses

1. Treatments which block or minimize delayed secondary injury will significantly decrease mortality and ultimate tissue damage after head trauma.



2. Treatments which block or minimize this secondary injury will improve the rate and quality of survival after head injury.
3. Treatments which block or minimize this secondary injury will significantly decrease the need for early intracranial debridement, and will thereby decrease surgical logistical requirements at or near the battlefield.
4. Predictors of both acute and long-term outcome after penetrating head injury can be determined, and can serve to guide therapeutic trials and patient care.

Objectives

The principal objective of this project is to develop simple medical treatments that can be administered to head injured patients by frontline medical personnel (and perhaps by the medic in the field), which will delay or minimize the need for definitive neurosurgery; and have the added benefit of minimizing mortality and ultimate tissue loss and thereby improving eventual neurologic outcome.

Interim Objectives

1. Establish a standardized, multicenter collaborative clinical research organization and methodology.
2. Study the metabolic, biochemical, and vascular responses to head injury in humans.
3. Determine predictors of mortality, and both short and long-term outcome after penetrating head injury. Develop and further refine practical therapeutic outcome criteria or endpoints for drug trials in head injury patients.
4. Conduct rigorous sequential therapeutic drug trials in head injured patients.
5. Refine the indications for intracranial neurosurgical debridement in the management of penetrating head injury.
6. Provide "*centers of excellence*" in head injury care, which can potentially serve as a research and training resource for military medical personnel.

Military Significance

Head injury is a major cause of combat mortality in the field (40% in Vietnam), and it accounts for a significant proportion of combat casualty care resources. The head injured patient almost invariably becomes initially unconscious or confused and, thus, not only loses all combat effectiveness immediately, but becomes a logistical burden from the commander's point of view. Field care for such patients has been purely supportive, but the standard of field hospital care involves definitive neurosurgery as soon as possible, i.e., close to the battlefield. The mean time to definitive neurosurgery in Vietnam was six hours postinjury. Not only is such prompt, highly specialized care unlikely in a massive conflict or in the fluid battlefields of the future, but it involves a tremendous personnel and logistical investment.

Logistically simple medical treatments which can minimize or delay the need for definitive neurosurgery and which can decrease mortality and improve ultimate outcome, can have a major impact on combat casualty care. Certain medical treatments to be investigated for brain injury may also be relevant to management of multitrauma, shock lung, burns, and/or chemical blistering agent exposure.

Progress to Date: Status Report

The overall objective of the APHIP is to establish a multicenter consortium that can conduct rigorous standardized scientific clinical trials in head injured patients; and then to use that collaborative system to study the pathophysiology and behavioral consequences of head injury and to develop and test promising new therapies and management strategies in such patients.

The first half of this objective has now been accomplished. A five university medical center network with a directorate has been established. Clinical centers were chosen by a formal source selection board from those responding to a formal RFP published by the USAMR&DC. The centers selected have exceptional credentials in head injury research, and adequate numbers of penetrating head injury patients. Three were participants in the National Traumatic Coma Data Bank (NTCDB), an NINCDS/NIH-sponsored study which, in part, served as base for development of our data collection system.

The centers are: Medical College of Virginia
 University of Texas, Galveston
 Baylor College of Medicine
 Louisiana State University/Tulane

After considerable discussions, standardized basic treatment algorithms and extensive multidisciplinary outcome parameters to be measured have been developed and agreed upon by all participants (see APHIP manual previously submitted). Personnel have been hired at the central office (a statistician/study manager, a neuropsychologist, a research coordinator, a research support specialist and a part-time programmer). At each remote site, a full time research nurse, a part-time MD head trauma fellow, a neurobehavioral tester, and a data management clerk have been hired. Several project meetings and training sessions have been conducted for all personnel in order to coordinate patient management, data gathering and other procedures. An administrative manual has been prepared.

A computerized data entry, editing, and polling system, including extensive data entry forms has been developed, tested in the field on over 50 patients, and finalized. The data collection forms themselves were partly derived from instruments developed by the NTCDB over a period of more than eight years. This has provided not only for independent validation of the instruments, but also for a wealth of comparable patient data that can serve as a historical control for our own studies. Multidisciplinary patient data which has undergone an extensive procedure of relational checks for internal and external validity is now being transmitted electronically to the project central office at USUHS. This procedure allows for correction of inconsistencies in the data while the patient is still hospitalized and records are still readily available. The computerized system has been designed to easily allow for inclusion of additional remote medical centers in the future.

Therapeutic Trials

The second half of the project, formal studies, has begun as of June 1989. Patients with very severe penetrating head injury (Glasgow Coma Score [GCS] 3-5) are now being randomized into a comparison trial of intracranial surgery versus medical intensive care, and patients with moderately severe injuries (GCS 6-15) are being entered into a descriptive study designed to help refine the best outcome parameters for therapeutic trials.

After extensive consideration of various therapeutic alternatives presently available, a promising new drug, superoxide dismutase (SOD) has been selected for the initial therapeutic trials. SOD, an oxygen free radical scavenger, is currently under investigation in a variety of other conditions, including multitrauma and acute respiratory distress syndrome, burns, coronary artery disease, and renal transplantation. Oxygen free radicals may also be involved in injury produced by chemical blistering agents such as mustard gas. SOD's mechanism of action in traumatic brain injury is not completely elucidated, but its effect may be either through its

effect on polymorphonuclear cells, or through its demonstrated reversal of the widespread microvascular changes produced by both closed and penetrating head injury.^{1,2,3} Dramatic benefit has been reported in some animal models of traumatic brain injury.^{4,5,6}

A collaborative agreement has been established with Biotechnology General Corporation, which produces human recombinant SOD and will supply it gratis to the project. The company also holds the FDA IND exemption for the drug. This particular preparation of SOD has been shown to be very safe in humans. Two protocols have been completed, and IRB approvals have been obtained from the four medical centers, USUHS, and The Surgeon Generals Human Use Committee. Randomization of the first patients into these drug trials is now projected for the Spring 1990, pending final FDA approval. Accession of patients into the descriptive study will continue through that time.

Ancillary APHIP studies include a national survey of over 3000 neurosurgeons regarding management of penetrating head injury. This has now been completed with over 35% response rate and shows wide variability and a surprising, general lack of consensus on the management of penetrating head injury (see manuscript, Appendix A). Other studies include continued analysis of long-term penetrating head injury outcome data generated in the Vietnam Head Injury Study (VHIS), as well as a detailed medical records review of penetrating spinal cord injury patients in our Vietnam registry (funded by the Veterans Administration).



ANDRES M. SALAZAR, M.D.
COL, MC
Professor of Neurology
Director, Army Head Injury Unit

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A NATIONAL SURVEY OF NEUROSURGICAL CARE FOR
GUNSHOT WOUNDS TO THE BRAIN

Howard H. Kaufman, M.D.
Professor and Chairman
Department of Neurosurgery
Health Sciences Center
West Virginia University
Morgantown, West Virginia 26506

Karen Schwab, M.A.
Biostatistician
Army Penetrating Head Injury Project
Uniformed Services University of the Health Sciences
Bethesda, Maryland

Andres M. Salazar, M.D.
Professor
Department of Neurology and
Director, Army Penetrating Head Injury Project
Uniformed Services University of the Health Sciences
Bethesda, Maryland

Running Title: GSW Survey

For Reprints: Howard Kaufman, M.D.
Department of Neurosurgery
3610 Health Science Center
West Virginia University Medical Center
Morgantown, West Virginia 26506

This study was carried out by the Army Penetrating Head Injury Project (APHIP), US Army Medical Research Development Command Contract #87PP7824.

ABSTRACT

It was not obvious that there was a consistent standard of care for gunshot wounds to the head. A survey of 2,969 American neurosurgeons was carried out to clarify this issue. Information was obtained from 38% about them, their practices, and their opinions concerning diagnostic testing, non-operative therapy, and surgical debridement. Areas of consensus (>75% agree) were noted. Where there was no consensus, factors influencing judgments were determined.

While there was consensus on use of CT, antibiotics, anticonvulsants, and several surgical indications / contraindications, there was wide variation on a significant number of issues. Many non-operative decisions were influenced by the presence of neurosurgical residents and practice at a Level I Trauma Center. Decision to operate was based on judgement of salvageability.

It is clear that there are variations in opinions about many crucial issues in the care of these patients, and this seems mainly due to the lack of relevant research.

Key Words: gunshot wounds, brain injuries, survey, treatment

INTRODUCTION

If trauma can be considered "the hidden epidemic", gunshot wounds (GSW) are probably its most obscure subcategory. This is despite the fact that firearms are among the twelve leading causes of death in the United States and the top ten causes of accidental death. Firearms are the etiology of 58% of homicides and 57% of suicides.¹ The frequency of nonfatal injuries is not available. A large proportion of the injuries involve the brain,² and an overwhelming percentage of brain injuries immediately or rapidly result in death.³⁻⁴

We have hypothesized that the common view and teaching about GSW to the brain is overly pessimistic and that failure to debride mass lesions on some occasions may lead to the inappropriate fulfillment of the prediction of a poor outcome.⁵ Indeed, we have reported unexpectedly good outcomes in patients shot through the geographic center of the brain² and remarkably little damage at a distance from the track of a bullet as reflected by psychological testing after recovery from the acute effects of the injury.⁶ This fits well with current concepts of wound ballistics which reveal that projectile injuries may not necessarily result in large volumes of injured tissue.⁷

There are many issues to be considered relative to the care of GSW to the head, including: 1. when is it necessary to decompress to salvage and how quickly this should be done, 2. the importance of debridement of brain, bone, and fragments to prevent swelling, bleeding, infection, and scarring,⁸ 3. whether

intracranial pressure is a good guide for treatment and what methods should be used to lower it, 4. is coagulopathy a significant factor in the pathophysiology of the injury, 5. are steroids helpful, 6 which antibiotics are most appropriate and how long they should be given, 7. whether and which prophylactic anticonvulsants should be used and for how long, and 8. what brain death criteria are satisfactory.

Additionally, there are issues which relate to ethical and legal considerations. For example, what should be done with an older patient who has less potential for recovery or a patient with terminal cancer attempting suicide? Is it important for a neurosurgeon to try to retrieve organs for transplantation, even to the point of resuscitating a patient only for this purpose? On the other hand, is it necessary to operate only to reassure the family that "everything is being done" or to protect oneself legally? Our personal experience in working in different locations and in speaking with many colleagues was that there were indeed large variations in opinions about these other issues.

In order to answer the question of whether or not there were important variations in the care of penetrating head injuries, we carried out a national survey of neurosurgeons, asking about their approach to various aspects of the care of victims of gunshot wounds to the head. Where we found variability, we tried to determine what factors might have led to that variability.

METHODS

The questionnaire we used was designed initially by the three investigators to examine demographic information about the neurosurgeons and their approach to the care of patients with GSW to the brain (Table I). It was informally pretested on approximately twenty colleagues. After adjustment, it was pretested formally on three independent random samples of 100 neurosurgeons each. These neurosurgeons' names were obtained from lists supplied by the American Association of Neurological Surgeons and the Congress of Neurosurgeons. Questionnaires were sent only to neurosurgeons living in the United States and its territories. The pretest revealed only minor difficulties and appropriate adjustments to the questionnaires were made. The final questionnaire had 43 questions, although several questions had a number of subquestions. Most required closed-ended responses, but some were open-ended. We then sent questionnaires to the remaining 2,669 neurosurgeons on the lists. Those that did not return the mailings were sent a second questionnaire. We eventually received a total of 1,128 replies from 2969 neurosurgeons (38%) of which 966 were from neurosurgeons who had been in active practice within the past two years and had seen patients with GSW and were used for the analysis. Further details on the design of the study and its implications are the subject of a separate report.

The responses were double entry key punched and analyzed with an IBM 370 using SAS Institute Software, Version 5, 1985. Bivariate and more complex analyses were carried out and tested

using logistic regression.

We defined consensus in treatment as occurring when 75% or more of neurosurgeons reported using a particular approach in their care of penetrating head injured (PHI) patients. For example, we asked how strongly hematomas influenced them to do or not to do surgery. Since over 75% (e.g. 92%) said they are influenced to do surgery in such patients, we considered operations in such cases to be the typical approach taken by neurosurgeons today. We also noted in which categories there was a 60-74% concurrence.

When we found variation (lack of consensus), we analyzed whether certain characteristics of the neurosurgeons and/or their practices might account for diagnostic or treatment choices they make. We used bivariate correlations, chi-square analysis, and multivariate logistic regression to determine whether variation in the use of tests/treatments was associated with length of time since the neurosurgeon finished his residency, "type of practice" (vide infra), percent of PHI cases due to assault, and whether there were neurosurgery residents in the hospital.

RESULTS

The demographic data revealed the average age of the respondents was 48 years \pm 9 (N = 956). They had been out of training 15 years \pm 9 (N = 940). Twenty-six percent had been in the military, but only six percent had seen combat. The ones with military and particularly combat experience were significantly older, as would be expected.

Respondents tended to practice in larger cities compared to the location of all the population, but spread with the population geographically (Table II). There were respondents from all states, as well as from the District of Columbia, the Virgin Islands and Puerto Rico. Respondents generally practiced in larger hospitals (Table II); 66% in private hospitals; and 26% in resident teaching centers. The average neurosurgeon saw nine penetrating head injury patients a year, but this was highly variable (S.D. 16.6). Most saw mainly handgun injuries ($81\% \pm 23$) as opposed to rifles ($10\% \pm 16$). In the average experience, assaults ($X 42\% \pm 29$) and suicides ($X 45\% \pm 28$) were seen with equal frequency, while accidents were more unusual ($X 15\% \pm 20$). Neurosurgeons in larger cities, at larger hospitals or at hospitals with Level I Trauma Centers see larger numbers of patients. The smaller the city, the more likely the injury will be related to suicide. Conversely, homicides are more common in larger cities.

The incidences of use of various tests and treatments are shown in Table III.

Testing for coagulopathy^{9,10} was done frequently (65% usually or always). The most common tests were the prothrombin time, activated partial thromboplastin time, and platelet count. Most did not use thrombin time, fibrinogen split products, or fibrinogen.

CT scanning" is used by 97% although it seems to be used by a few less to make the decision of whether or not to operate (i.e. some use it more for surgical planning).

Prophylactic antibiotics were generally used (87%). The duration of treatment was seven days or less in 63% of responses (Table IV). Multiple antibiotics were used by 438 respondents - two by 320 respondents, three by 80 respondents and four or more by 32 respondents. The most commonly used antibiotics were cephalosporins (440), chloramphenicol (176), penicillins (117), aminoglycosides (88), vancomycin (47), miconazole (26), tetracycline (20), and erythromycin (19). Although the question asked about routine coverage, it is not clear that each respondent used this many antibiotics in each patient. Estimation of infection rates for penetrating wounds also varied (Table V).

Anticonvulsants are used prophylactically by 84% of respondents, and 98% of these use phenytoin. Of these, 88% load the drug, 60% adjust by blood level, while 20% give 300 mg/day and 20% give 400 mg/day. Thirty-five percent use phenobarbital, generally in combination with phenytoin. Medications are used most often for a year or less (Table III). Twenty-two percent will switch to carbamazepine.

Corticosteroids are used routinely by 42% of respondents.

Thirty-six percent use ultrasound at the time of surgery.

Intracranial pressure monitoring remains controversial. A few respondents indicated they might use it without debridement (13% usually or always), while a few (7% usually or always) would use it to determine whether or not to operate. Forty percent of neurosurgeons reported using ICP monitoring "usually" or "always" in patients with Glasgow Coma Scores of 6-8 (Table III).

Only 37% ever use barbiturate coma, of whom 83% use it with ICP monitoring. The threshold pressure at which it is used is variable (Table III).

Multivariate regression analysis of which physician/practice characteristics determined the decision to use tests/treatments showed that the presence of neurosurgery residents was the most important (Table VI). Neurosurgeons practicing in centers with neurosurgery residents report more frequent testing for coagulopathy and use of CT; less frequent use of steroids; and more frequent use of intraoperative ultrasound, ICP monitoring of patients with GCS 6-8, antibiotics, and anticonvulsants, but not barbiturate coma.

The interaction of practice in a Level I center and the presence of neurosurgery residents leads to a nearly 100% reported use of coagulation tests. The effect of these two characteristics upon treatment choices is more than additive and is best captured with a multiplication combination of the two. This interaction effect was also significant for steroids and barbiturate coma ($p < .0001$).

Another set of questions involved what determined the decision on whether or not to treat with intracranial surgical debridement. To demonstrate the responses, we have reproduced the questions, collapsed the data from seven categories to three (influence against surgery, neutral, influence for surgery), and indicated which questions received consensus answers, that is 75% agreement in one of the three final categories, as well as how many received

agreement of 60% (Table VII). Of the 29 reasons presented in the questionnaire for operating/not operating on patients with penetrating head injuries, neurosurgeons reached consensus on eight, and 60-74% agreed on another eight (Table VII). Areas in which consensus was reached included low GCS categories, bilateral pupillary dilation, CSF leaks, elevation of depressed fractures, primary removal of bone fragments and hematomas.

Not only was there lack of consensus, but there was considerable disagreement on need for surgery in those patients with the middle range of GCS scores. More than half do not feel it is necessary to remove retained bone or bullet fragments, even if they are copper. There was no agreement on the importance of the location of the bullet in the dominant hemisphere or its having crossed the ventricles, although most neurosurgeons do not operate on deep wounds or those that have crossed the midline. The patient's age, e.g. 65 years or older, or whether the patient was a suicide attempt likewise tend not to influence them in so far as the question of operating or not operating.

Again, we wondered whether the neurosurgeon/practice characteristics explain some of the variation which does occur in self-reported tendency to operate. We also wondered whether the neurosurgeon's general view on the salvageability or nonsalvageability of PHI patients influences his tendency to operate.

Non-salvageable patients were defined by 68% of respondents as those expected to die, while 30% add those expected to survive

in a vegetative state, and only 2% add those expected to survive with a severe disability. We asked, "In your experience, what percentage of the following penetrating head injured patients are ultimately salvageable?" In general, one would expect the outlook for PHI patients would vary by GCS level. The responses reflect that concept. Salvageability is generally not expected with GCS 3 and 4, but it is in patients with 9-12 and 13-15, although perhaps not to the extent reported in the literature (Fig. 1). Interestingly, although almost no one was optimistic about the most severely injured patients, or very pessimistic about patients with less severe injuries, there was considerable variation around the average responses.

We compared the assessments of salvageability made by neurosurgeons who saw large numbers with those who saw fewer, by those who had served in the military as neurosurgeons versus those who had not, and by those working in Level I versus other trauma centers. We also compared the judgement of those who reported lower rates of infection in patients with those reporting higher rates of infection. Only the issue of infections correlated with the physician's perception of ultimate salvageability of these patients and only for GCS 9-12, 13-15.

Multiple logistic regression analysis showed that the neurosurgeons' perceptions of patient salvageability was an important predictor of tendency to operate. In fact, of the variables we examined, it was the only factor significantly associated with tendency to operate on severely injured patients

(GCS 8 or less). The larger the percentage of patients seen as ultimately salvageable within an injury class (i.e. GCS levels), the more likely the neurosurgeon was to report he tends to operate on that group of patients. The variable significantly related to tendency to operate in the less severely injured patient was length of time since the neurosurgeon's residency. That relationship was negative, meaning the longer the neurosurgeon had been in practice, the less likely he was to operate on those patients (GCS 9-12 and 13-15).

Nevertheless, 80% of neurosurgeons will sometimes-to-always put "unsalvageable" patients into an ICU, although only 70% will sometimes-to-always ventilate them. Decisions to carry out such treatment is influenced by questions of legal liability (66% sometimes-to-always), to show the family something being done (66% sometimes-to-always), and for organ procurement (89% sometimes-to-always). Most respondents (85%) say they do not treat suicides differently.

From the responses, it appears the generally accepted standard surgical technique is in widespread use. This includes craniotomy (83%) or craniectomy (82%), following the track deep into the brain (75%), and patching the dura (86%), especially with autogenous tissue (79%). Over half (532) do not use artificial dura, while 48% never use human prepared dura. As mentioned before, 36% use ultrasound fairly frequently. According to 68%, surgery should be performed as soon as possible, and another 15% felt it should be performed within a day.

Of the many brain death criteria,¹² 48% use the Harvard Criteria of 1968, 6% use the NIH Combined Study Criteria of 1977, and 12% use the criteria of the President's Commission of 1981. No particular characteristics of physicians or their practices distinguished those who used the most recently proposed criteria, those of the President's Commission. Thirty-four percent use other criteria. Eighty-one percent of respondents' hospitals have specific brain death criteria.

Seventy-five percent state they have a hospital policy regarding organ retrieval. Ninety-one percent feel their medical examiner is "sometimes to always" cooperative with retrieval. Sixty-six percent "sometimes to always" request donation in homicide, and 70% feel they are successful in half or less of these cases. However, 86% "sometimes to always" request in suicide, but 65% feel they are successful in half or less of these cases.

DISCUSSION

[The advantages of the survey approach are considerable - we were able to obtain a national sample of physician practices (very difficult to obtain in record review studies); the standardized items facilitated the testing of our hypotheses about variation in care; and we have the physicians' own judgement concerning current practices in the treatment of penetrating head injuries. The neurosurgeons responded at rates found in mail surveys of other populations and the questionnaires appeared to have been thoughtfully filled out. Because of the heavy time commitments of

neurosurgeons and length and complexity of the survey - five pages of detailed questions - we had expected lower return rates. Indeed, many surgeons provided lengthy additional assessments. We are confident the data portray the variation which exists in opinions about and the type of care given penetrating head injuries patients.]

[There were indications of the neurosurgeons' concern about their own ability to make educated decisions.] On the last page of our questionnaire, a number of respondents took the opportunity to state their opinions about the treatment of PHI. Some expressed frustration over the lack of information about the outcome of PHI treatments, and pointed to the need for research. Even though many of the severely injured cases are not seen as very salvageable, many neurosurgeons feel treatment is the only hope and worry about patients who might have had good survival if full treatment was given. Others worry about the devastating effects upon family members/society/the patient himself if he survives but with severe handicaps.

The fact that there is such variation in the approach to the treatment of gunshot wounds to the head is not unreasonable when one considers certain historical facts. Current attitudes, including the military's emphasis on early debridement, are likely based by some on an extensive experience going back to the writings of Cushing and others from World War I.^{3-5, 13-36} However, attitudes based on opinions generated many years ago ought to be placed in the perspective of current experience. For example, early

resuscitation and rapid transport to trauma centers, as well as prevention and treatment of complications, permit salvage of certain patients who would previously have died.

The recent literature has described optimal treatment of severe closed head injuries as including early resuscitation with intubation and rapid transport to a center which has the capability for definitive treatment,³⁷ use of CT scanner to detect clots, even in the presence of artifacts from bullets,¹¹ early removal of mass lesions,³⁸ and management of intracranial pressure elevations,³⁹⁻⁴² including the use of barbiturate coma.⁴³ New antibiotics may be more effective in preventing infections. The use of anticonvulsants has been improved by ability to measure blood levels. Steroids have been found not to be efficacious, and indeed in some respects are harmful.⁴⁴⁻⁴⁶ Fifty eight percent of respondents, particularly those in academic centers, do not use them.

A critical, comprehensive review of the literature about civilian gunshot wounds to the head has been prepared.⁴⁷ Newer studies reflect the adoption of the Glasgow coma scale, CT scanning, and the Glasgow outcome scale. However, there are variations in the literature in suggestions with regard to all aspects of care. This is consistent with the variation in practice patterns noted in this study. In addition, although detailed analysis are not possible due to difficulty in comparing different series, there is a trend toward better survival rates in series with higher operative rates (Fig. 2).^{4, 5, 14, 15, 21, 23, 25, 27, 31, 36} Our data suggest that this may in turn reflect opinions regarding salvageability.

The situation we have described, namely a tremendous variation in treatment and lack of a clear standard of care of a significant medical problem, is not unusual. Perception and consideration of this problem has been receiving more scrutiny over the last few years, and the study of usefulness of treatment modalities across a disease is now termed formally "technology assessment." This is a broad subject. The Office of Technology Assessment (OTA) of the US Congress has defined technology to include drugs, devices, medical and surgical procedures, and the organizational and supportive systems within which medical care is provided.⁴⁸ And OTA has suggested that only 10 - 20% of medical technologies have been properly evaluated in the rigorous setting of prospective randomized trials.⁴⁹⁻⁵¹

Although many organizations are pursuing technology assessment,⁵² it is obvious that improvement in coordination is required. Some striking examples about variability of care for other diseases include: 1) two to three fold variations in surgical rates in Massachusetts for 18 operations;⁵³ 2) at least threefold differences in the use of 54% (67/123) procedures among Medicare beneficiaries in 13 different regions in the United States;⁵⁴⁻⁵⁷ 3) over a threefold variation of caesarean rates across 19 industrialized countries;⁵⁸ and 4) variations in the management of carotid artery plaques, murmurs, and transient ischemic attacks across the specialties of medicine, neurology, neurosurgery, surgery, and others.⁵⁹ Only the last study was based on a survey. It has been pointed out that these variations may be due to both

undertreatment or overtreatment, or that ultimate outcomes may be the same in areas where risk and benefit are similar and therefore the range is reasonable and expected,⁶⁰⁻⁶³ although judgments have been made such as inappropriate performance of carotid endarterectomy.⁶⁴ It has been well emphasized there is a need for quality care, a need to carefully evaluate competing technologies, and alternatively a risk of allowing the health care system to be too driven by cost constraints.⁶⁵ Improved assessment might be accomplished by coordination at the national level, possibly by a dual private-public consortium.^{66,67} It should be emphasized that the existence of consensus does not necessarily indicate optimum treatment. For example, while our survey shows consensus on the removal of bone fragments, recent research indicates this may not be needed.^{68,69} Properly conducted clinical studies should be the principal guide for establishing optimal care.

CONCLUSIONS

There is considerable difference of opinion among neurosurgeons as to what is appropriate in the management of penetrating head injury. This relates to decisions about surgical debridement, use of ICP monitoring, and non-operative treatment modalities. The presence of neurosurgery residents was the most significant demographic factor related to most of their choices. However, the neurosurgeons' assessment of a patient's salvageability determined the decision whether or not to operate.

The variation in the care provided to penetrating head injured patients may be partly explained by several factors:

- 1) The traditional military standard of care for penetrating head injury emphasizes early surgical debridement, while the modern civilian approach seems derived from the treatment of closed head injuries and is based on the medical control of intracranial pressure and the use of newer antibiotics for contamination.
- 2) Victims of GSWs have been viewed so pessimistically that studying them has been felt to be futile, and there are few systematic investigations of aggressive management.
- 3) Many treatments have not been subjected to rigorous testing, and thus there is variation of opinion regarding different treatments, and a variation in practice.
- 4) Those teaching residents will find it easier and will be encouraged to provide more aggressive and innovative care.

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LEGENDS

Figure 1. The percent of patients felt to be salvageable for a given Glasgow Coma Score or group of Coma Scores. N = 1015 Neurosurgeons. ± 1 S.D.

Figure 2. Percent of patients surviving versus percent of patients operated in several series. Numbers in figure indicate references.

Table I. Areas Investigated in Questionnaire

Demographics

Age
Time from residency
Military/combat experience
Size of city
Section of country
Size/type of hospital
Trauma center level
Number of PHI/year
Assault/suicide/accident
Type of weapon
Neurosurgery residents

Patient Care

Screening for coagulopathy
CT
Antibiotics
Anticonvulsants
Steroids
Reason to operate/not operate
Surgical technique/timing
ICP monitoring
Brain death criteria
Organ retrieval
Social/ethical issues
Legal issues

Table II. Demographic Characteristics of Respondents

<u>City Size</u>	<u>Neurosurgeons (%)</u>	<u>Population (%)</u>
<100,000	20	75
100,000 - 500,000	34	13
500,000 - 1,000,000	18	5
>1,000,000	28	8

<u>Region</u>	<u>Neurosurgeons (%)</u>	<u>Population (%)</u>
Northeast	18	21
South	36	34
Central	23	25
West	23	20

<u>Beds</u>	<u>Neurosurgeons (%)</u>	<u>All Hospitals (%)</u>
<400	39	88
400 - 800	49	10
>800	12	2

Table III. Percent of Responding Neurosurgeons Using Various
Neurosurgical Evaluations and Treatment for Penetrating
Brain Wounds

	<u>% Respondents</u>
Do you usually or always test for Coagulopathy	65
Do you evaluate with CT	97
Do you use Prophylactic Antibiotics	87
Do you use Anticonvulsants	84
Time	
6 months	30
1 year	43
2 years	19
Longer	9
Do you use Corticosteroids routinely	42
Do you use Ultrasound	36
Do you usually or always use	
ICP Monitoring if GCS 3-5	30
if GCS 6-8	40
if GCS 9-12	25
if GCS 13-15	16
Do you use Barbiturate Coma	37
Threshold pressure (mm Hg)	
15 - 20	6
21 - 25	23
26 - 30	31
31 - 35	17
36 - 40	10
> 40	12

Abbreviations: CT, computerized tomography; ICP, intracranial pressure; GCS, Glasgow Coma Score

TABLE IV.
Distribution of Neurosurgeons who routinely use antibiotics in
patients expected to survive and number of days used (N-750)

<u>Days</u>	<u>Neurosurgeons</u>	
	<u>%</u>	<u>Cumulative %</u>
1	4	4
2	9	13
3	11	24
4	5	29
5	14	43
6	5	48
7	15	63
8	3	66
9	9	75
10	13	88
11	1	89
12	2	91
13	-	91
14	8	99
15 +	2	101

Table V. Estimated Infection Rates (N = 812)

<u>% Infection</u>	<u>% Respondents who Estimate This Infection Rate</u>
0	21
1 - 5	33
6 -10	28
11-25	12
≥ 26	6

Table VI. Influences on Management
(Logistic Regression Analysis)
Beta(p)

	Intercept	Years Out	Number (10+) Seen/Yr	Level I Trauma Center	% PHI Assault	Nsurg Resident	Model Y2 ChiSquare (p value)
Test for Coagulopathy	.491	-.031 (.0004)	N.S.	N.S.	.009 (.001)	1.206 (.0001)	70.20,3d.f. (.0)
Use of Steroids	-.372	N.S.	-.395 (.018)	N.S.	.010 (.0004)	-1.002 (.0001)	46.77,3d.f. (.0)
Use of Ultrasound	-.893	N.S.	N.S.	N.S.	N.S.	1.083 (.0001)	41.43,1d.f. (.0)
Use of ICP Monitors	-.720	N.S.	N.S.	N.S.	N.S.	1.017 (.0001)	34.57,1d.f. (.0)
Use of Barbiturate Coma	-.688	N.S.	N.S.	N.S.	N.S.	.678 (.0001)	16.74,1d.f. (.0)

Table VII. Percent of Neurosurgeons Indicating the Effect of Different Parameters on Their Decisions to Operate

	No Surgery (%)	Neutral (%)	Surgery (%)	Consensus
Hematoma	1	7	92	+
Contusion	39	32	29	
Edema with mass effect	46	23	31	
Remove bone fragments	4	6	90	+
Bone fragments remaining after first debridement	31	21	49	
Remove bullet or metal fragments	45	24	31	
Metal fragments remaining after first debridement	71	19	10	±
Copper jacketed bullets	39	26	36	
Medico-legal pressure	45	34	21	
To reassure family	49	33	18	
To prevent delayed edema or infection	16	14	69	±
To prevent or repair CSF leak	4	8	88	+
Elevation of depressed fracture	3	7	90	+
GCS 3	82	10	8	+
GCS 4	73	16	12	±
GCS 5	50	29	21	
GCS 6-8	12	34	55	
GCS 9-12	7	16	77	+
GCS 13-15	10	14	77	+
One pupil dilated	10	19	72	±
Both pupils dilated	77	14	9	+
Location:				
(1) Dominant hemisphere	32	39	29	
(2) Deep brain	70	20	10	±
(3) Cross midline	60	26	13	±
(4) Cross ventricle	52	32	17	
Did not respond to resuscitation				
(1) Hyperventilation	68	20	12	±
(2) Mannitol	68	19	13	±
Age, e.g., 65 and older	44	40	16	
Suicide	32	52	16	

GCS - Glasgow Coma Score

+ - consensus reached by >75% in one category, ± - 60%-74% agreement. Respondents were asked to evaluate "Reasons why you would or would not operate on penetrating wounds to the head. Please consider each item in isolation from the others. How strongly does this influence you to operate." The answer categories were labelled as: 0-2 = No surgery, 3 = Neutral, 4-6 = Surgery.



